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Guidance for the Reregistration of Pesticide Products Containing Dicrotophos as the Active Ingredient

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EPA

Guidance for the Reregistration of Pesticide Products Containing DICROTOPHOS as the Active Ingredient

DICROTOPHOS

Pesticide Registration Standard

April 1982

Office of Pesticides and Toxic Substances
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CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

A. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter involves the regulatory position and the rationale supporting this position. The third chapter sets forth the data requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use the pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

The Standard will directly register or reregister only manufacturing use products and their intermediaries. End-use products will be registered or reregistered under a separate Label Improvement Program. The only exception to this general rule will arise when there is no manufacturing use product registered for a particular end-use product. In this case, the end-use product will be treated as if it were a manufacturing use product.

The Agency has separated the reregistration of end-use products from that of manufacturing use products in order to increase the rapidity with which products may be reregistered and to place emphasis on the concern for chronic health effects data which prompted the legislative requirement for reregistration. The utility of this approach is the product of two factors. First, end-use product specific data requirements are minimal and can be more effectively handled through a separate process. Second, a separate process obviates many of the difficulties inherent in reregistration of products which are mixtures of more than one active ingredient and will ultimately be affected by several Standards. Under the Label Improvement Program, end-use products will be reregistered on a separate schedule from the reregistration of manufacturing use products.

The Standard will consider all uses of the active ingredient which are registered for end-use products at the time the Standard is developed, including use patterns which pertain only to mixtures. The Standard will also establish labeling requirements for manufacturing use products which formulators of end-use products will have to follow. However, the imposition of these labeling requirements directly on formulators will fall under the Label Improvement Program.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific, i.e. data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2. Generic data that pertains to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any manufacturing-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's are irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.)

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed guidelines, 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide.

If a registrant of a currently registered manufacturing-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that are required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered are all data which are described by all of the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;
2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain an existing registration;
3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);
4. The Agency has found the data to be valid and usable in reaching regulatory conclusions

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for those data.

Each applicant for registration or reregistration of a manufacturing-use product must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data.

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" — in accordance with a schedule. Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

Chapter II

Regulatory Position and Rationale

A. Introduction
B. Description of Chemical
C. Regulatory Position
D. Regulatory Rationale
E. Criteria for Registration Under the Standard
F. Acceptable Ranges and Limits
G. Required Labeling
H. Tolerance Reassessment

A. Introduction

This chapter presents the Agency's regulatory position based on an evaluation of the use patterns of all registered products containing dicrotophos as the sole active ingredient or in combination with other active ingredients in a mixture. The regulatory position contained in the Standard reflects a review of only this chemical and not of other active ingredients in a mixture.

After briefly describing dicrotophos, this chapter presents the regulatory position and rationale, as well as the criteria for registration of products containing this chemical. These criteria include labeling considerations and requirements related to tolerance reassessment. A summary of data requirements is contained in the data requirement tables.

B. Description of Chemical

Dicrotophos (dimethyl phosphate ester of 3-hydroxy-N,N-dimethyl-cis-crotonamide) is a restricted use insecticide and miticide registered for use by certified applicators on cotton, soybeans grown for seed, and ornamental trees. Dicrotophos is also known by the trade names Bidrin®, Carbicron®, and Ektafos®. An IR-4[1] minor use petition for the use of dicrotophos on pecans is currently undergoing review at EPA. The American Chemical Society's Chemical Abstracts Service (CAS) number for dicrotophos is 141-66-2 and the EPA Shaughnessy number is 035201. Technical grade dicrotophos is registered for formulation into an emulsifiable concentrate, a soluble concentrate, and a ready-to-use solution.

C. Regulatory Position

Dicrotophos as described in this Standard may be registered for sale, distribution, reformulation, and use in the United States. The Agency has considered the scientific data obtained from the open literature as of July 1, 1981. Based upon the review of these data, the Agency finds that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded for

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1/ IR-4 is the Interregional Research Project based at the New Jersey Agricultural Extension Service at Rutgers University. It is a cooperative program of State and Federal Agricultural scientists to register minor uses of pesticides.

dicrotophos. The Agency has determined that dicrotophos has not been demonstrated to cause unreasonable adverse effects in man when used in accordance with prescribed label directions and precautions. Although the RPAR criterion for avian subacute dietary toxicity cannot be fully assessed without the required environmental fate data, a field test on birds (see Tables III. A-2 and III. A-5), and information on the frequency of repeat applications, an examination of the available toxicity data indicates that the avian dietary criterion may indeed be exceeded for cotton and soybean use patterns. This possibility will be fully evaluated when all the relevant data are available. Dicrotophos products currently registered may be reregistered subject to the conditions imposed by this chapter, and to the data requirements identified in the data requirement tables. New products may be registered under this Standard and are subject to the same requirements.

D. Regulatory Rationale

A review of the available data regarding the manufacturing-use products of dicrotophos shows that much information that could be used to support registration and reregistration is not available. The Agency has the prerogative not only to request information to satisfy the data Guidelines proposed in 1978 and 1980, but may also require additional testing. These additional tests may be requested by the Agency if it believes that particular concerns regarding the health or environmental effects of a pesticide must be evaluated. In some cases, this additional testing may be deferred pending the Agency's review of specific test protocols developed by the registrant or the completion of other related tests the Agency requires for registration of a manufacturing-use product (e.g., tiered testing).

It is the policy of the Agency not to automatically request guideline information only because a particular guideline exists. Each element of the guideline is considered individually with regard to the pesticide's uses, exposure, and risk. If the Agency concludes that specific elements of the data guidelines are required to prepare a comprehensive Registration Standard, the data will be required.

Available toxicological data indicate that dicrotophos has a high acute dermal and acute oral toxicity to mammals. Also, the ecological effects data indicate that dicrotophos has a very high acute oral and subacute dietary toxicity to birds. Accordingly, a Federal Register Notice was issued January 19, 1981 (46 FR 5696) classifying dicrotophos as a restricted use pesticide. Effective June 10, 1981, any pesticide product containing 8% or more dicrotophos is limited to use by or under the supervision of a certified applicator. Currently there are no registered pesticide products containing less than 8% dicrotophos. Any new registration application for a pesticide product containing less than 8% dicrotophos will be reviewed to determine if the product should be restricted to use by certified applicators.

Despite the existing data gaps, the Agency has concluded that the registration of this chemical should continue for the following reasons:

1) Although dicrotophos has been shown to have adverse acute toxic effects to humans, these effects should not pose a hazard when dicrotophos is used by or under the supervison of certified applicators in accordance with label instructions.

2) Although the July, 1981 Pesticide Incident Monitoring System (PIMS report) lists 22 incidents acute in nature involving dicrotophos as the only active ingredient, these incidents involved primarily non certified and non commercial users and occurred prior to the classification of dicrotophos as a restricted use pesticide. The presentation of information regarding incident exposure circumstances and effects in the PIMS report is made with no reference to whether the occurrence has been confirmed to be the result of pesticide involvement. Use of dicrotophos by or under the supervision of certified applicators in accordance with label instructions should not pose any acute hazards to humans.

3) Although an examination of the available data suggests that the RPAR criterion for avian subacute dietary toxicity may be exceeded in the cotton, soybean and ornamental use patterns, available data are insufficient to make a final determination. A complete evaluation of avian toxicity will be made when the required information on environmental fate, avian field testing and frequency of repeat applications per year is available. Also, before this required information is available, based on the known avian dietary toxicity of dicrotophos EPA will initiate a request for a formal consultation with the U.S. Department of Interior pursuant to Section 7 of the Endangered Species Act. This action is necessary for the Agency to be in compliance with the Act.

4) In accordance with FIFRA, the Agency's policy is not to cancel or to withhold registration merely because of the lack of data [See Sections 3(c)(2)(B) and 3(c)(7) of FIFRA]. Rather, publication of the Standard provides a mechanism for identifying data needs, and registration under the Standard allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency. The Agency will then determine whether these data will affect the registration of this chemical.

E. Criteria for Registration Under the Standard

To be subject to this Standard, products must meet the following conditions:

- contain dicrotophos as the sole active ingredient or in combination with other active ingredients in a mixture
- bear required labeling; and
- conform to the acute toxicity limits, product composition, and use pattern requirements stated in Section F below.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in this Standard including a commitment to fill data gaps on a time schedule specified by the Agency as indicated in the Guidance Package, and, when applicable, an offer to pay compensation to the extent required by Section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). As discussed in Chapter I and in the Guidance Package, applicants for registration under this Standard must contact the Registration Division for specific instructions, including updated information contained in the Guidance Package on data requirements, and contact companies whose data must be cited and to whom compensation must be offered.

F. Acceptable Ranges and Limits for Manufacturing-Use Products

a. Product Composition Range

To be covered under this Standard, manufacturing-use dicrotophos products must conform to the requirements stated below:

Active Ingredient:	Any percentage acceptable.
Inert Ingredient:	Only those inert ingredients which are cleared under the Federal Food, Drug and Cosmetic Act are acceptable fpr use in manufacturing-use products which are to be formulated into end-use pesticides intended for use on growing crops. Refer to 40 CFR 180.1001(c) and (d) for a listing of such cleared inert ingredients. There are no restrictions on the percentages of inerts currently being used to formulate the manufacturing-use products included in this Standard.

b. Acute Toxicity Limits

Because this pesticide is acutely toxic, all uses are restricted to certified applicators only. The Agency will consider registration of manufacturing-use products in the toxicity categories indicated by a "yes."

	I	II	III	IV
Acute Oral Toxicity	yes	yes	yes	yes
Acute Dermal Toxicity	yes	yes	yes	yes
Acute Inhalation Toxicity	yes	yes	yes	yes
Primary Eye Irritation	yes	yes	yes	yes
Primary Dermal Irritation	yes	yes	yes	yes

c. Use Patterns

To be covered under this Standard, manufacturing-use dicrotophos productsmust be labeled to allow formulation into end-use insecticides and/or miticides, which are intended only for the following use patterns. In data to be submitted or cited, all manufacturing use dicrotophos product labels must bear one or a combination of these use patterns.

1. Outdoor non-domestic, terrestrial, food use (crop foliar application)
2. Outdoor, non-domestic, terrestrial, food use (tree injection application)
3. Outdoor, domestic/non-domestic, terrestrial, non-food use (ornamental foliar application)
4. Outdoor, domestic/non-domestic, terrestrial, non-food use (tree injection application)

G. Required Labeling

1. Manufacturing-Use Products

All dicrotophos manufacturing-use products must conform with the labeling requirements specified in 40 CFR 162.10 and bear a label statement which provides that the product may be used only in the formulation of insecticide and/or miticide products registered by the United States Environmental Protection Agency. Because of the acute toxicity of dicrotophos all manufacturing use products must bear a label statement which includes the following:

> "This pesticide is toxic to fish and wildlife. Do not discharge into lakes, streams, ponds, or public water unless in accordance with NPDES permit. For guidance, contact your State or EPA Regional Office.

2. End-Use Products

Although this Standard applies only to dicrotophos manufacturing-use products, as a result of the review of the dicrotophos data base and the classification of dicrotophos as a restricted use pesticide, additional label modifications will be required for dicrotophos end-use products. These label modifications are discussed below and will be addressed as part of EPA's Label Improvement Program (see 45 FR 37884).

The human hazard precautionary statements are to be segregated according to the various routes of exposure, with the routes producing the greatest hazard being listed first. The statements must be consistent with those provided by the Guidance Package.

Effective June 10, 1981, any pesticide product containing 8% or more dicrotophos is classified as a restricted use pesticide and, must bear the following statement:

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

In accordance with Worker Protection Standards For Agricultural Pesticides (see 40 FR 425) the following reentry statement is required for all end-use products intended for ornamental or crop use:

> Do not enter a field within 48 hours of treatment unless you wear clean protective clothing.

In conjunction with the restricted use classification, the following environmental hazard statement pertinent to the potential effect of dicrotophos application on fish and wildlife must also appear on all end-use products except those intended for tree injection use only:

> This pesticide is extremely toxic to fish and wildlife. Birds in treated areas may be killed. Do not apply directly to lakes, streams, ponds or wetlands. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

The Agency has additionally noted that dicrotophos poses a threat to honey bees. In this regard, all end-use products except those intended for tree injection use only must bear the following environmental hazard statement:

> "This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

H. Tolerance Reassessment

A U.S tolerance of 0.05 ppm (negligible residue) has been established for residues of dicrotophos in or on cottonseed. A tolerance of .05 ppm for residues of dicrotophos and its metabolite, monocrotophos, in or on pecans has been proposed by the Interregional Research Project No. 4. In Mexico, a tolerance of 0.05 ppm has been established for residues of dicrotophos on cottonseed, sorghum, and wheat. There are no Canadian tolerances for dicrotophos. The Codex Alimentarius Commission has not recommended maximum residue limits for dicrotophos on any commodity.

In calculating the theoretical maximum residue contribution (TMRC) the Agency assumes that the chemical is applied to all commodities on which its use is authorized, that each commodity contains the maximum level allowed in the tolerance, and that average 60-kilogram adult eating patterns result in 100 percent of the dicrotophos-treated food in the adult diet of 1.5 kilogram per day. The TMRC of dicrotophos in the human diet from cottonseed is calculated to be 0.00011 mg/day.

There have been no reported incidents of over-tolerance residues of dicrotophos on cottonseed; however, Food and Drug Administration has not monitored for residues of dicrotophos on cottonseed and thus the absence of monitoring data is not necessarily an indicator of compliance with the tolerance on cottonseed.

Although dicrotophos is currently registered for use on soybeans grown for seed, there is no tolerance for residues of dicrotophos on soybeans. At the time that dicrotophos was registered for this use, the application of pesticides to crops grown for seed was considered a non-food use. Subsequent experience has shown that, upon leaving grower control, residue-bearing seed is sometimes used for food or feed, although dicrotophos is not approved for this use; consequently, a tolerance petition is now required for pesticides applied to soybeans grown for seed.

For the continued registration of dicrotophos on seedcrop soybeans, a tolerance proposal with supporting data is required. Included in this proposal should be the results of analyses of the raw agricultural commodity for residues of dicrotophos and its cholinesterase-inhibiting metabolites, and residue data on processed oilseed fractions if residues are found in the seed. Data on residues in meat and milk may also be required if significant residue levels are present in soybeans or soybean fractions.

III. SUMMARY OF DATA REQUIREMENTS

Applicants for registration of dicrotophos manufacturing-use products must cite or submit the information identified as required in the tables in this chapter. Data generated on one formulation may be used to satisfy the data requirement for a substantially similar formulation. Information on which product specific data requirements are already met is available in the Guidance Package and in Tables III B-1 and B-2 of this standard.

The section of the Proposed Guidelines which describes the type of data and when the data are required to be submitted [43 FR, 29696 of July 10, 1978; and 43 R, 37336 of August 22, 1978] is listed with each requirement. Justification for why the test is required is provided in the Guidelines. Discussions of why data additional to those already submitted are necessary, or why data normally required are not necessary for this chemical, are presented in footnotes to the tables. The data requirements specified are the minimum that will be required. Areas where additional data may be required as the result of tiered testing (e.g., requiring certain baseline data to determine the need for additional data) are indicated.

Dicrotophos

Table III. A-1 Generic Data Requirements[1]: Product Chemistry (See Chapter IV)

Guideline Citation	Name of Test	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)2(B)? If so, when?
163.61-3	Product Identity and Disclosure of Ingredients	Technical Grade of Active Ingredient	no	—	yes[2], 6 mos.
163.61-4	Description of Manufacturing Process	Technical Grade of Active Ingredient	partial[3]	000013814 000013513	yes, 6 mos.
163.61-5	Discussion of Formation of Unintentional Ingredients	Technical Grade of Active Ingredient	partial	GS0003505	no[4]
163.61-7	Analytical Methods and Data	Technical Grade of Active Ingredient	partial [5]	000014004 005016160 005013477 005012700	yes, 6 mos.
163.61-8(c)(1)	Color	Technical Grade of Active Ingredient	yes	000013435 005013057	no
163.61-8(c)(2)	Odor	Technical Grade of Active Ingredient	yes	000013435	no
163.61-8(c)(4)	Solubility	Technical Grade of Active Ingredient	yes	000013435 005016160	no

[1] Unless otherwise noted the data are required for all uses.

[2] An updated Confidential Statement of Formula is required.

[3] Although a sketchy manufacturing procedure has been submitted. A detailed procedure is required.

[4] A discussion concerning the presence of nitrosamines in technical dicrotophos has been submitted. Agency acceptance of the discussion is reserved pending receipt of a detailed manufacturing procedure.

[5] Satisfactory methods for the determination of dicrotophos per se in the technical material are available but analytical data have not been submitted. Methods for the determination of and data on impurities in the technical material have not been submitted.

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Table III.A-1 Generic Data Requirements: Product Chemistry (See Chapter IV)

Guideline Citation	Name of Test	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)2(B)? If so, when?
163.61-8(c)(5)	Stability	Technical Grade of Active Ingredient	yes	000013435 005013057	no
163.61-8(c)(6)	Octanol/Water Partition Coefficient	Analytical Grade of Active Ingredient	not applicable 1/	-	no
163.61-8(c)(7)	Physical State	Technical Grade of Active Ingredient	yes	000013435	no
163.61-8(c)(8)	Density or Specific Gravity	Technical Grade of Active Ingredient	yes	000013435	no
163.61-8(c)(9)	Boiling Point	Technical Grade of Active Ingredient	yes	000013435 005013057 005016160	no
163.61-8(c)(10)	Vapor Pressure	Analytical Grade of Active Ingredient	yes	000013435	no
163.61-8(c)(11)	pH	Technical Grade of Active Ingredient	no	-	yes, 6 mos.

1/ The test is required for nonpolar organic pesticides, and is therefore inappropriate for dicrotophos.

Dicrotophos

Table III. A-2 Generic Data Requirements: Environmental Fate [1/] (See Chapter V)

Guideline Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when?
163.161-1	Hydrolysis	Technical or Radiolabeled Analytical Grade	no	—	yes, 8 months
163.161-2	Photodegradation in water	Technical or Radiolabeled Analytical Grade	no	—	yes, 8 mos.
163.161-3	Photodegradation in Soil	Technical or Radiolabeled Analytical Grade	no	—	yes, 8 mos.
163.161-4	Photogradation in Air	Technical or Radiolabeled Analytical Grade	no	—	yes[2/], 8 mos.
163.162-1	Aerobic Soil Metabolism	Technical or Radiolabeled Analytical Grade	partial	000013470 000028571	yes[3/], 18 mos.
163.162-2	Anaerobic Soil Metabolism	Technical or Radiolabeled Analytical Grade	no	—	yes, 18 mos.
Reserved	Effects of Microbes on Pesticides 4/	—	—	—	—
Reserved	Effects of Pesticides on microbes 4/	—	—	—	—
Reserved	Activated Sludge Metabolism 4/	—	—	—	—

[1/] All the environmental fate data requirements apply to ornamental (foliar application) and crop use only, except 163.165-1 and 163.165-2 which apply to crop use only except for tree fruit/nut crops. These data requirements are current as of March 1982. Refer to the Guidance Package for updated requirements.

[2/] Required by the Agency on a case-by-case basis, depending on the Agency's evaluation of data derived from laboratory volatility tests, Section 163-2(b)(2).

[3/] As required by the guidelines the studies do not show level (ppm) and identity of degradation products with time. A study must be conducted for 2 halflives or 6 months.

[4/] The requirement for these data is being reserved pending the development and modification of test protocols.

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Table III. A-2 Generic Data Requirements: Environmental Fate (See Chapter V)

Guideline Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when?
163.163-1	Leaching	Technical or Radiolabeled Analytical Grade	no	—	yes, 8 months
163.163-2	Laboratory Volatility	Typical End-Use Product of major formulation category	no	—	yes, 8 mos.
163.163-3	Field Volatility	Typical End-Use Product of major formulation category	no	—	yes,[1] 8mos.
163.164-1	Field Dissipation-Terrestrial	Typical End-Use Product of major formulation category	partial[2]	000013512	yes, 12 mos.
163.164-5	Dissipation-Long Term Studies	Typical End-Use Product of major formulation category	no	—	yes[3], 24 mos.

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[1] Required by the Agency on a case-by-case basis depending on the Agency's evaluation of data derived from laboratory volatility tests, Section 163.163(2)(b)(2).

[2] The study satisfies the requirement for one site (clay loam soil). A study on another site representative of where dicrotophos is used (e.g. cotton belt) is required, unless the dissipation rate shown by tests per Section 163.162-1 or 163.164-1 is less than 50% prior to subsequent application.

[3] Long-term field dissipation studies will be required if the dissipation rate shown by tests per Section. 163.162-1 or 163.164-1 is less than 50% prior to subsequent application.

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Table III. A-2 Generic Data Requirements: Environmental Fate (See Chapter V)

Guideline Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, whens?
163.165-1	Confined Accumulation Rotational Crops	Technical or Radio-labeled Analytical Grade	no	—	yes, 24 months
163.165-2	Field Accumulation-Rotational Crops	Typical End-Use Product of major formulation category	no	—	yes[1/], 36 mos.
163.165-5	Field Dissipation-Aquatic Non-Target	Typical End-Use Product of major formulation category	no	—	yes[2/], 24 mos.
Subpart K	Reentry	Typical End-Use Product of major formulation category	partial	000013471	no[3/],

1/ Required only when significant C^{14} residues are found, Section 163.165-1, or when subsequent crop is treated with the same a.i., as initial crop.

2/ Field dissipation studies in aquatic non-target organisms are required to support the registration of each manufacturing-use product:

- o Which is intended for forestry use, aquatic non-crop use, or aquatic impact use that results in direct discharges;
- o For which data from a laboratory fish accumulation study are required by Section 163.165-4; or
- o For which no tolerance or action level for fish has been granted

Since for dicrotophos there is currently no tolerance or action level for fish this study is required.

3/ A reentry time of 48 hours has been established per 40 CFR 170. The labels must be revised to include this requirement or for each crop, the registrant may propose a new reentry interval; this proposed interval may be based on any of the following:

(a) the longest (most restrictive) existing reentry intervals;
(b) data on dissipation of foliar residues (decline curve), on human exposure to those residues, and on the inherent toxicity of the chemical;
(c) determination of that time beyond which there are no detectable foliar residues (under appropriate climatic conditions) in the area where the chemical will be applied.

Either the longest (most restrictive) reentry interval is acceptable, or the exposure data and a dislodgeable residue curve, together with the inherent toxicity of the chemical, may be used to establish an appropriate interval for activities that result in foliar contact. The longest (most restrictive) reentry intervals will be listed by crop.

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Table III. A-3 Generic Data Requirements: Toxi 1/ (See Chapter VI)

Guidelines Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when?
163.81-1	Acute Oral Toxicity	Technical Grade of Active Ingredient	partial 2/	000013869	yes, 8 months
163.81-2	Acute Dermal Toxicity	Technical Grade of Active Ingredient	yes	000013869 000028521	no
163.81-3	Acute Inhalation Toxicity	Technical Grade of Active Ingredient	partial 3/	000013443	yes, 14 months
163.81-4	Primary Eye Irritation	Technical Grade of Active Ingredient	yes	000013869	no
163.81-5	Primary Skin Irritation	Technical Grade of Active Ingredient	no	-	yes, 14 months
163.81-6	Dermal Sensitization	Technical Grade of Active Ingredient	no	-	yes, 14 months
163.81-7	Acute Delayed Neurotoxicity	Technical Grade of Active Ingredient	yes	000013444	no
163.82-1	Subchronic 90-Day Oral	Technical Grade of Active Ingredient	partial 4/	000013564 000013869 000013441	yes, 14 months
163.82-2	Subchronic 21-Day Dermal Toxicity	Technical Grade of Active Ingredient	no	-	yes, 14 months

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1/ Data requirements for Sections 163.81-1, 163.81-2, 163.81-3, 163,81-4, 163.81-5, 163.81-6 and 163.81-7 apply to all uses; data requirements for Sections 163.82-1, 163.82-2, 163.83-3, 163.83-4, 163.84-2 and 163.85-1 apply to ornamental (foliar application) and crop use (foliar application) only; and the remaining data requirements apply to crop use (foliar application) only.

2/ The rat study satisfies the requirement for males but a study in females rats is required.

3/ The rat study satisfies the requirement for males but a study in female rats is required. If the acute oral study indicates no difference in the toxicity to male and female rats, this requirement is satisfied.

4/ MRID# 00013441 is a valid study and will satisfy this requirement if an acceptable pathology report is provided. The other studies only partially satisfy the data requirement.

Table III. A-3 Generic Data Requirements: Toxicology (see Chapter VI)

Guideline Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when?
163.83-1	Chronic Feeding	Technical Grade of Active Ingredient	no	-	delayed 1/
163.83-2	Oncogenicity	Technical Grade of Active Ingredient	no	-	delayed 1/
163.83-3	Teratogenicity	Technical Grade of Active Ingredient	partial 2/	GS0003501	yes 2/, 24 months
163.83-4	Reproduction	Technical Grade of Active Ingredient	no	-	delayed 1/
163.84-2	Mutagenicity	Technical Grade of Active Ingredient	yes	GS0003502 GS0003506	no
163.85-1	Metabolism	Analytical Grade	partial 3/	000013450	yes, 24 months

1/ The Agency is delaying a decision concerning these requirements pending the results of the following: residue chemistry data requirements on cottonseed, processed cotton seed, soybeans, and processed soybeans; and an applicator exposure study including data on applicator dermal and inhalation exposure. If these studies show no chronic exposure, the chronic toxicity studies will be waived; conversely, if the potential for chronic exposure is demonstrated, the studies will be required. Protocols for conducting the residue chemistry and applicator exposure studies must be submitted and approved by the Agency prior to their initiation and these studies must be completed within 12 months.

2/ The study is acceptable for rabbits but a study in rats is required.

3/ The rat study is acceptable for males but a study is required for female rats unless the acute oral study indicates no sexual difference in oral toxicity or the studies in footnote 1/ show no chronic exposure.

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Table III. A-4 Generic Data Requirements: Resid mistry[1] (See Chapter VII)

Guideline Citation[2]	Name of Test	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)2(B)? If so, when?
—	Metabolism in Plants	Radiolabeled Dicrotophos	partial [3]	000013998 005013986 000013451 00013506 005014733 000013684	yes, 12 mos.
—	Metabolism in Food-Producing Animals	Radiolabeled Dicrotophos	yes	005012698 005014733	no
—	Analytical Methods and Data	Analytically Pure Dicrotophos and Its Oxidative Metabolites [4]	yes	000013682 000013472 000013703 000013474 000013456 000014005 000013517 000013453 000013967 000013969 000014006 000013999 000013516 005002358	no

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[1] The residue chemistry data requirements apply to crop use only.

[2] Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and, the Agency believes are relatively familar to registrants.

[3] Data on the nature of the residue in the foliage of dicrotophos-treated plants have been submitted; however, there are no data on whether residues in cotton foliage are transferred to cottonseed (see footnote 4/).

[4] Metabolites produced by oxidative demethylation of dicrotophos.

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Table III. A-4 Generic Data Requirements: Residue Chemistry[1] (See Chapter VII)

Guideline Citation	Name of Test	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)2(B)? If so, when?
—	Residues in Crops				
	Sample Handling Procedures	Pure Dicrotophos & Its Oxidative Metabolites [2]	no	—	yes[3], 12 mos.
	Cottonseed (Raw Agricultural Commodity)	Representative Formulation	partial [4]	000013684 000014000 000013997	yes, 12 mos.
	Processed Cottonseed	Residue-Bearing Cottonseed	no	—	yes[5], 12 mos.
	Soybeans (Raw Agricultural Commodity)	Representative formulation	no	—	yes[6], 12 mos.
	Processed Soybeans	Residue-Bearing Soybeans	no	—	yes[5], 12 mos.
	Pecans	Representative Formulation	partial[7]	GS0003504	no
	Residues in Food-Producing Animals				
	Meat	Active Ingredient	partial[8]	000013440	no
	Milk	Active Ingredient	yes	000013440 005012698	no

[1] Protocols for conducting the residues studies must be submitted and approved by the Agency prior to the initiation of the studies.

[2] Metabolites produced by oxidative demethylation of dicrotophos.

[3] Information on the handling of residue samples prior to analysis are required. For samples analyzed more than 2 months after sampling, data on the stability of residues under the conditions of sample storage are needed.

[4] Analyses of cottonseed for residues of dicrotophos per se have been submitted. Additional data on residues of cholinesterase inhibiting metabolites of dicrotophos in cottonseed are required unless additional metabolism data are submitted which demonstrate that such metabolites are not present in cottonseed. If no detectable residues of dicrotophos and its cholinesterase-inhibiting metabolites are found in cottonseed from treated cotton no further residue or metabolism data for cottonseed will be required. In addition residue data reflecting aerial application are required.

F notes for Table III. A-4 continued

5/ If res data requested under this Standard demonstrate the presence tectable residues in the raw agricultural commodity, then a fractionation study on a representative oilseed crop (e.g., cottonseed or soybeans) is required.

6/ In order to maintain the use of dicrotophos on soybeans grown for seed, a tolerance proposal is required.

7/ Dicrotophos-treated pecans were analyzed for dicrotophos and monocrotophos, but not for the oxidative metabolites of dicrotophos. The Agency is not concerned with the oxidative metabolites in this case because of the low contribution of pecans to the human diet.

8/ Additional data on the level of tissue residues in dicrotophos-fed food-producing animals may be required if other data requested under this standard indicate that the present tolerance on cottonseed is inadequate, or if significant residue levels are shown to exist on dicrotophos-treated soybeans grown for seed.

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Table III. A-5 Generic Data Requirements: Ecological Effects 1/ (see Chapter VIII)

Guideline Citation	Name of Test	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when?
163.71-1	Avian Single-Dose Oral LD_{50}	Technical Grade of Active Ingredient	yes	000014011 005008363	no 2/
163.71-2	Avian Dietary LC_{50}	Technical Grade of Active Ingredient	yes	000022923	no
163.71-4	Avian Reproduction	Technical Grade of Active Ingredient	no	—	reserved 3/
163.71-5	Simulated and actual Field Testing for Mammals & Birds	Formulation (8LB/gal) SC/L	no	—	yes 4/, 24 months
163.72-1	Fish acute LC_{50}	Technical Grade of Active Ingredient	yes	GS0003503	no
163.72-2	Acute Toxicity to Aquatic Invertebrates	Technical Grade of Active Ingredient	no	—	yes 5/, 14 months
163.72-4	Fish Early Life Stage Aquatic Invertebrate Life Cycle	Technical Grade of Active Ingredient	no		reserved 6/

1/ The ecological effects data requirements apply to all uses except 163.71-4, 163.71-5 and 163.72-4 apply to ornamental (foliar application) and crop (foliar application) use only.

2/ Although neither of the cited studies is adequate to satisfy the guideline requirement, when considered collectively, the data are sufficient to fulfill the avian acute oral LD_{50} requirement.

3/ The avian reproduction study is reserved pending results of the required environmental fate data.

4/ A field test on birds is required because of high avian acute toxicity. A protocol for conducting this study must be submitted and approved by the Agency prior to initiation of the study. This field test must include information on the frequency of repeat applications for all uses.

5/ Immature aquatic invertebrates are assumed to be more sensitive than adults; their LC_{50} would enable a standard hazard assessment to be performed.

6/ The aquatic invertebrate life-cycle requirement is reserved pending results of the required environmental fate data.

Dicrotophos

Table . B-1 Product Specific Manufacturing-Use Products Data Requi ..its: Product Chemistry (See Chapter IV)

Guideline Citation	Name of Test	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)2(B)? If so, when?
163.61-3	Product Identity and Disclosure of Ingredients	Each Product	no[1]	—	yes, 6 mos.
163.61-4	Description of Manufacturing Process	Each Product	no	—	yes, 6 mos.
163.61-5	Discussion of Formation of Unintentional Ingredients	Each Product	no	—	yes, 6 mos.
163.61-6	Declaration/Certification of Ingredients Limits	Each Product	no	—	yes, 6 mos.
163.61-7	Product Analytical Methods and Data	Each Product	partial[2]	000014004 005016160 005013477 005012700	yes, 6 mos.
163.61-8(c)(1)	Color	Each Product	no	—	yes, 6 mos.
163.61-8(c)(2)	Odor	Each Product	no	—	yes, 6 mos.

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[1] Updated Confidential Statements of Formula are required.

[2] Satisfactory methods for the determination of dicrotophos *per se* in products are available but analytical data have not been submitted.

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Table III. B-1 Product Specific Manufacturing-Use Products Data Requirements: Product Chemistry (See Chapter IV)

Guideline Citation	Name of Test	Composition	Does EPA Have Data To Partially Or Totally Satisfy This Requirement?	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA 3(c)2(B)? If so, when?
163.61-8(c)(7)	Physical State	Each Product	yes	Product Label	no
163.61-8(c)(8)	Density or Specific Gravity	Each Product	no	—	yes, 6 mos.
163.61-8(c)(11)	pH	Each Product	no	—	yes, 6 mos.
163.61-8(c)(12)	Storage Stability	Each Product	no	—	yes, 6 mos.
163.61-8(c)(13)	Flammability	Combustible Liquid Products	no	—	yes, 6 mos.
163.61-8(c)(14)	Oxidizing/Reducing Action	Each Product	no	—	yes, 6 mos.
163.61-8(c)(15)	Explosiveness	Each Product	no	—	yes, 6 mos.
163.61-8(c)(16)	Miscibility	Liquid Products	no	—	yes, 6 mos.
163.61-8(c)(17	Viscosity Coefficient	Liquid products	no	—	yes, 6 mos.
163.61-8(c)(18)	Corrosiveness	Each product	no	—	yes, 6 mos.

Table III. B-2 Product-Specific Manufacturing-use Products Di hos Requirements: Toxicology (See Chapter VI)

Guidelines Citation	Name of Test	Are Date Required for this Standard	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, when?
163.81-1	Acute Oral Toxicity	yes	Each manufacturing-use product	no	—	no[1]
163.81-2	Acute Dermal Toxicity	yes	Each manufacturing-use product	no	—	no[1]
163.81-3	Acute Inhalation Toxicity	yes	Each manufacturing-use product	no	—	no[1]
163.81-4	Primary Eye Irritation	yes	Each manufacturing-use product	no	—	no[1]
163.81-5	Primary Dermal Irritation	yes	Each manufacturing-use product	no	—	no[1]
163.81-6	Dermal Sensitization	yes	Each manufacturing-use product	no	—	no[1]
163.81-7	Acute Delayed Neurotoxicity	yes	Each manufacturing-use product	no	—	no[1]

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[1] The acute toxicity studies are required for labeling purposes. If the severest labeling restriction (i.e., the signal word "DANGER" and a skull and crossbones) appears on the manufacturing-use label, these requirements will not apply.

IV. PRODUCT CHEMISTRY

A. Chemical Identity
B. Manufacturing Process
C. Discussion of the Formation of Unintentional Ingredients
D. Declaration and Certification of Ingredient Limits
E. Product Analytical Methods and Data
F. Physical and Chemical Properties
G. Summary of Major Data Gaps

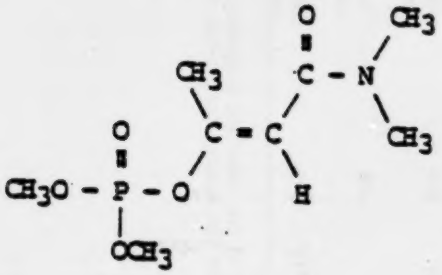
A. Chemical Identity

Dicrotophos (Figure 1) is the common name accepted by the International Organization for Standardization (ISO) and the British Standards Institution (BSI) for the dimethyl phosphate ester of 3-hydroxy-N,N-dimethyl-cis-crotonamide. Alternative chemical names for dicrotophos include: dimethyl cis-2-dimethylcarbamoyl-1-methylvinyl phosphate and 3-dimethoxyphosphinyloxy-N,N-dimethylisocrotonamide.

Dicrotophos is also known by the trade names Bidrin®, Carbicron®, and Ektafos®. The Chemical Abstracts Registry (CAS) number for dicrotophos is 141-66-2, and the EPA Shaughnessy number is 035201. The Shell Develpment Company code number is SD 3562 and the CIBA AG code number is C709. The ISO common name is used throughout this standard in lieu of other chemical or trade names.

Figure IV-1

Dicrotophos



B. Manufacturing Process

Two process descriptions for the manufacture of technical grade dicrotophos have been submitted to the Agency by Shell Chemical Company (1962, 000013814; 1976, 000013513). Neither of the process descriptions is sufficiently detailed to satisfy Guidelines requirements.

C. Discussion of the Formation of Unintentional Ingredients

The Agency has made a preliminary determination that there is little likelihood of nitrosamine contamination of dicrotophos manufacturing-use products, and that analytical data for nitrosamines, over and above that already submitted by registrants, are not required at this time. A final determination will be made upon receipt and evaluation of a detailed manufacturing process for technical dicrotophos.

D. Declaration and Certification of Ingredient Limits

For no dicrotophos-containing manufacturing-use product has the registrant established upper and lower limits for the active ingredient and each intentionally added inert ingredient, and upper limits for each identifiable impurity as required by the Guidelines (Section 163.61-6).

E. Product Analytical Methods and Data

Infrared spectrophotometric and gas chromatographic methods are available for analyzing dicrotophos. For infrared analysis, liquid samples are diluted with carbon tetrachloride or methylene bromide, and the spectrum of the solution is recorded from 10.5 to 11.09 microns. The concentration of dicrotophos in the product is determined from a calibration curve using the absorbance at 10.8 microns. Solid samples may be analyzed in a similar manner after a preliminary extraction step (Shell, 19??, 000014004; Porter, 1967, 005016160).

For gas chromatographic analysis, liquid samples are diluted with acetone and aliquots injected on a suitable column equipped with either a flame ionization detector or a thermal conductivity detector. Concentration of dicrotophos in the product sample is determined from comparison of sample and standard peak heights or areas (Shell, 1972, 005013477).

Data obtained by the above methods or by other methods must be submitted in support of certified limits for dicrotophos in the technical material. Data for impurities in technical dicrotophos and the methods by which the data were obtained must also be submitted in support of certified limits.

Spectral data are sometimes required by the Agency for identification purposes (Section 163.61-7). Mass spectra of dicrotophos have been published (Busch et al. 1978, 005012700).

F. Physical and Chemical Properties

The physical and chemical properties of dicrotophos are as follows:

Color: The color of dicrotophos is reported as brown (Shell, 19??, 00013435); or pale straw colored (Brown, et al., 1966, 05013057).

Odor: The odor of dicrotophos is described as "mild ester" (Shell, 19??, 000013435).

Solubility: Dicrotophos is miscible (mixable in all proportions) with water, acetone, alcohol, acetonitrile, chloroform, methylene chloride, and xylene. It is slightly soluble in kerosene and diesel fuel (Shell, 19??, 00013435; Porter, 1967, 005016160).

Stability: Dictrotophos is "stable when stored in glass or polyethylene containers. Formulations unstable on most solid carriers; acidic solutions are more stable than basic solutions." The half-life of dicrotophos in water varies from 50 days at pH 9 to 100 days at pH 1 (Shell, 19??, 000013435). Technical dicrotophos decomposed 5% after 1 year of storage at 30°C, or after 5 years of storage at 20°C (Brown et al., 1966, 005013057).

Octanol/Water Partition Coefficient: Although this test is required for nonpolar organic compounds, this test is not appropriate for dicrotophos because of its solubility in water and polar organic solvents (see above) and its partition properties (Seiber and Markle, 1972, 05012561; Shell 19??, 000013435).

Physical state: Dicrotophos is a liquid at 25°C (Shell, 19??, 000013435).

Density or Specific Gravity: The density of dicrotophos is 10.1 lb/gal (1.21 gm/ml) at 20°C. The specific gravity is 1.22 (16°/16°C) (Shell, 19?? 000013435).

Boiling Point: The boiling point of dicrotophos has been variously reported as 117°C at 0.001 mm Hg (Shell, 19??, 000013435), 90°-95°C at 0.001 mm Hg (Porter, 1967, 005016160), and 138°C at 0.6 mm Hg (Brown et al., 1966, 005013057).

Vapor Pressure: The vapor pressure of dicrotophos is 1×10^{-4} mm Hg at 20°C (Shell 19??, 000013435).

G. Summary of Major Data Gaps

The following data are required: (1) a detailed manufacturing process for technical dicrotophos; (2) updated Confidential Statements of Formula for all products, the Statements to include certification of ingredient limits; (3) analytical methods and data supporting the certified limits for dicrotophos and impurities in the technical material; and (4) certain data on the physical and chemical properties of dicrotophos-containing products.

V. ENVIRONMENTAL FATE

A. Use Summary
B. Environmental Fate Profile
C. Exposure Profile
D. Summary of Data Gaps

A. Use Summary

Dicrotophos is an insecticide and miticide registered for use on cotton, soybeans grown for seed, and ornamental trees. Ninety-one percent of the dicrotophos used annually is for control of insects on cotton, largely cotton fleahoppers, lygus bugs, and thrips. Soybeans and ornamental trees are relatively minor use sites. Dicrotophos is formulated as 7.5 and 8.0 lb. ai/gal soluble concentrate/liquids (SC/L) and as an 86% ai ready-to-use formulation (RTU). The SC/L formulations are applied by aerial or ground equipment to agricultural crops, while the sole RTU formulation, manufactured as a specialized trunk injector unit, is used on ornamental trees. All dicrotophos formulations are registered for application by or under the supervision of certified applicators only.

B. Environmental Fate Profile

Only limited data are available to assess the environmental fate of dicrotophos.

Four aerobic soil metabolism studies were reviewed. Two were found to be valid and were combined into a single review which is summarized below. Osgerby and Clarke, 1965 (000013470) and Osgerby and Woodburn, 1965 (000028571) found that dicrotophos degradation in soil (clay, sandy loam, and sandy clay loam) follows first-order kinetics and is microbially mediated. The enzymes responsible for metabolism are apparently synthesized continuously. The half-life is 3-15 days. Metabolism of technical dicrotophos (90% ai) occurs at approximately twice the rate of granular (5% ai) formulations.

One study on the effects of microbes on dicrotophos was reviewed and was found to be valid. Osgerby and Woodburn, 1965 (000028571) found that 95% of the initial amount of dicrotophos (unspecified formulation) was lost after 12 days in a soil-inoculated nutrient medium. The loss was largely attributed to microbial metabolism since only 25% of the dicrotophos was lost from a sodium azide-sterilized nutrient solution over the same period. The requirement for these data is being reserved pending the development and modification of testing protocols.

One study on the terrestrial field dissipation of dicrotophos was found to be valid. Elgar and MacDonald, 1966 (000013512) found that dicrotophos (5% ai granular), applied at 2, 4, or 8 lb/A, dissipates rapidly from a clay loam soil. The half-life was <1 week and no dicrotophos was detected 8 weeks after application. A study on another site representative of where dicrotophos is used (e.g. cotton belt) is required unless the dissipation rate shown by tests per Section 163.162-1 or 163.164-1 is less than 50% prior to subsequent application.

One study pertaining to the dissipation of foliar dicrotophos residues was reviewed and found to be valid. Bull and Lindquist, 19?? (000013471) found that only 16-31% of the radioactivity applied to cotton leaves or cotyledons as ^{32}P dicrotophos remained as water-dislodgeable residues after incubation in a greenhouse for 24 hours. Dislodgeable residues declined at similar rates from treated leaves and cotyledons.

The submitted data are insufficient to assess the environmental fate of dicrotophos.

C. Exposure Profile

Data are not available to fully assess the potential for exposure of humans and wildlife to dicrotophos. Applicator inhalation exposure is possible through foliar application to cotton, ornamentals and soybeans grown for seed and mixing and loading operations. Human dermal exposure is possible, but should be mitigated with labeling requirements for protective clothing. Exposure associated with the injection use of dicrotophos on ornamental trees should be negligible since both the injection unit and the sites (trees) are closed systems. Also, wildlife exposure is possible from foliar application.

Data are needed to assess the potential for dicrotophos to contaminate groundwater. The high miscibility of dicrotophos with water indicates that leaching could lead to groundwater contamination and damage to nontarget organisms. Whether the rapid degradation of dicrotophos in soil (Osgerby and Clarke, 1965, 00013470; Osgerby and Woodburn, 000028571) will partially negate any leaching hazard is unknown. A greenhouse study (Bull and Lindquist, 19?? 000134710 showed that 16-31% of the applied ^{32}P, remained as dislodgeable residues 24 hours after ^{32}P dicrotophos was applied to leaves of cotton plants. The decline of dislodgeable dicrotophos residues under field conditions is unknown.

Exposure associated with the use of the RTU formulation appears to be negligible since both the injection unit and the sites (trees) are closed systems and since the sites are treated locally and represent minor uses.

The SC/L formulations pose an exposure risk to humans during mixing and loading operations due to splashing and during application due to spray drift. In addition, dislodgeable plant residues, and possibly dicrotophos vapors, pose a reentry exposure risk according to the use pattern. Protective clothing and masks or respirators would minimize such exposure.

D. Summary of Data Gaps

The following generic data are required: hydrolysis studies; photodegradation studies in water, on soil, and in air; aerobic and anaerobic soil metabolism studies, leaching, laboratory volatility, and field volatility studies; terrestrial and long-term field dissipation studies; confined and field rotational crop accumulation studies; and field studies of accumulation in non-target aquatic organisms.

VI. TOXICOLOGY

- A. Toxicology Profile
- B. Human and Domestic Animal Hazard Assessment
- C. Summary of Data Gaps

A. Toxicology Profile

1. Acute Effects

The acute oral LD_{50} of technical dicrotophos in male Long-Evans rats was reported as 22 (19-25) mg/kg. The acute oral LD_{50} of technical dicrotophos in male Swiss Webster mice was reported as 12.6-15.8 mg/kg (Shellenberger and Newell, 1962, 000013869). The rat study satisfies the requirement for males but a study in females is required.

The following supplemental[2] acute oral toxicity data are also available. The acute oral toxicity of technical dicrotophos in various solvents was determined in young adult Carworth Farm rats. Sexes were combined in this study (Brown et. al, 1964, 000013438). The results are presented in Table VI-1.

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[2] Supplementary data are data which, although not fulfilling a specific data requirement, may have some useful information (e.g., a range finding study).

Table VI-1

Acute Oral Toxicity of Technical Dicrotophos In Various Solvents [1]

	Technical Dicrotophos	Dicrotophos 24% w/v2/ Isopropyl Alcohol	Dicrotophos 24% w/v Dimethyl sulphoxide
LD_{50} (mg/kg)	12.8	28.7[3]	30.2[3]
95% confidence limits	9.1-15.7	23.3-34.1	24.7-36.5

1/ from Brown et al., 1964, 000013438
2/ weight per volume or w/v
3/ As Dicrotophos without solvent

The acute oral toxicity of technical dicrotophos in various solvents has also been determined for CF_1 mice (Brown et al., 1964, 000013438). Sexes were combined in this study. The approximate LD_{50} of 2% dicrotophos (weight per volume, w/v in isopropyl alcohol) was 20 mg/kg and the approximate LD_{50} of 1% dicrotophos (w/v in dimethyl sulphoxide) was 40-50 mg/kg.

The acute oral toxicity of technical dicrotophos to rats (sex not specified) was reported by Witherup and Schlecht (1962, 000028521) as being 32.7 ± 2.5 mg/kg.

The acute dermal toxicity of technical dicrotophos in the rabbit was reported to be 224 (103-505) mg/kg (Schellenberger and Newell, 1962, 000013869) and 149 ± 18 mg/kg (Witherup and Schlecht, 1962, 00028521). The latter study satisfies that acute dermal toxicity data requirement.

The acute inhalation LC_{50} of technical dicrotophos in male Charles River CD rats was reported to be between 0.48 and 0.72 mg/liter (Witherup et al., 1965, 000013443); an inhalation toxicity study is required in female rats, however.

Technical dicrotophos was reported to be a very mild eye irritant in the rabbit (Shellenberger and Newell, 1962, 000013869). This study satisfies that primary eye irritation data requirement.

Single oral doses of technical dicrotophos up to an acute LD_{50} (7.4 + 0.7 mg/kg) did not produce signs of acute delayed neurotoxicity in hens (Witherup et al., 1963, 000013444). A single oral dose of 8 mg/kg technical dicrotophos (the LD_{50}) in atropine and protopam-protected hens produced no signs of acute delayed neurotoxicity. Lack of suitable control groups and insufficient information on histopathology, however, made proper evaluation of this study impossible (Boom and Forigan, 1965, 00014010).

In summary, technical dicrotophos has a high acute oral toxicity with LD_{50} values ranging from 12 to 30 mg/kg in the rat. The toxicity does not appear to be significantly affected by the solvent used. The acute dermal toxicity is also high, with an LD_{50} of 224 mg/kg reported in the rabbit. Also, a high acute inhalation toxicity, with an LC_{50} of between 0.48 and 0.72 mg/L, was reported in the rat. Dicrotophos does not produce organophosphate-type delayed neurotoxicity. Due to the high acute toxicity, this has been classified as a restricted use pesticide.

2. Subchronic Effects

In a 12-week feeding study of dicrotophos in young adult Long-Evans rats, the only effect reported was depression of weight gain at a dietary level of 135 ppm both sexes and 45 ppm females. A no-observable-effect level (NOEL) of 15 ppm was established. Insufficient animals were used, however, and they were not weanlings; the study is therefore classified as supplementary (Shellenberger and Newell, 1962, 000013869).

Also, weanling Long-Evans rats were studied for the effect of dicrotophos on whole blood and brain cholinesterase. For both sexes whole blood cholinesterase was depressed at dietary levels of 4.5 and 1.5 ppm but not at 0.5 ppm in both sexes. There was a statistically significant depression of brain cholinesterase at the 4.5 ppm dose level. There was a similar depression, although not statistically significant, at the 1.5 ppm dose level and no effet at the 0.5 ppm dose level. Whole blood activity returned to normal within two weeks and brain activity within three weeks after cessation of treatment. A NOEL for depression of brain and whole blood cholinesterase activity was established at 0.5 ppm. Various deficiencies required the classification of this study as supplementary (Shellenberger and Newell, 1962, 000013869). In the subchronic testing in rats, the major toxic effects were depression of weight gain and depression of cholinesterase activity.

A 13-week feeding study of dicrotophos in young beagle dogs at dietary levels of 1, 5, and 50 ppm showed depression in red blood cell (RBC) and brain (50 ppm) cholinesterase activity. These effects occurred only at the 50 ppm dose level and were the only signs of toxicity. This study is considered supplementary because the pathologist's report was not included (Witherup et al., 1964, 000013441).

A 2-year feeding study of dicrotophos in beagle dogs at 0.16, 16, and 100 ppm revealed signs of toxic effects at 100 ppm (salivation, soft stools, and/or tremors) (Johnson et al., 1967, 000013564). Significant decreases in plasma and RBC cholinesterase were observed at 16 and 100 ppm but not at 1.6 or 0.16 ppm. A NOEL of 1.6 ppm was established for depression of plasma and RBC cholinesterase activity. Damage to the pyloric region of the stomach was observed in 2 of 3 females at 100 ppm. The high dose animals were only treated for one year. Insufficient animals were tested and the study was classified as supplementary.

A subchronic 21-day dermal toxicity study included application of technical dicrotophos to the skin of rabbits at doses of 20 and 40 mg/kg/day for 21 days (Doyle and Elson, 1965, 00005117). No compound-related toxicity was observed. The study is classified as supplementary because these doses produced no effect and a maximum dose of 2000 mg/kg was technically feasible to apply.

Five consecutive daily oral doses of technical dicrotophos given to hens at 2.4 mg/kg/day produced no neurotoxic effect during a 21-day observation period (Brown & Ferrigan, 1965, 000014010). This study is classified as supplementary because, the dose was not administered for the required period.

A subchronic neurotoxicity study which included repeated dosing of 15 hens with technical dicrotophos at daily doses of 1.5 mg/kg/day twice during the first week and 0.75 mg/kg/day five times per week during the second and third weeks (Witherup et al., 1963 000013444). No signs of delayed neurotoxicity were produced. These studies failed to demonstrate organophosphate-type delayed neurotoxicity and are classified as supplementary because the dose was not administered for the required period. Testing is not required since the acute neurotoxicity test was negative.

3. Chronic Effects

In a 2-year feeding study, dicrotophos caused excessive mortality, compared to controls, in male rats at all doses (1, 10, and 100 ppm) and in female rats at 10 and 100 ppm (Johnson, 1966, 000013966 and Howard et al., 1967, 000013563). Plasma cholinesterase was depressed at all doses in both sexes and RBC cholinesterase at 10 and 1,000 ppm in both sexes. Growth was depressed at 100 ppm in both sexes. The study does not satisfy Agency requirements since it lacked sufficient animals at the start, surival was less than 20 percent in most treated groups, and a NOEL was not demonstrated.

Oral teratogenicity studies were performed in Dutch Belted rabbits (Dix, Wilson, et al., 1973, GS0003501) Technical dicrotophos was administered on days 6-18 of pregnancy at doses of 1.3, 4, or 8 mg/kg/day. Thalidomide, at doses of 37.5 or 75 mg/kg/day, was used as a positive control. Although, maternal toxicity including signs of cholinesterase inhibition, was observed at 8 mg/kg/day, no fetal toxicity attributable to dicrotophos was observed at this dose. Teratogenicity was demonstrated at the maximum thalidomide dose of 75 mg/kg/day.

Young adult rats fed dicrotophos at 0.3, 3.0, and 30 ppm for up to 25 weeks showed no toxic effects (Witherup et al., 1964, 000013445). Breeding and fertility were normal in the two matings per animal. No gross teratogenic effects were observed. Survival of offspring at 30 ppm was severely affected, with 80 percent mortality for the first mating and 93 percent mortality for the second mating during the first week.

Dicrotophos at 50 ppm in the diet of pregnant rats caused an increase in the number of embryos absorbed (9.7% vs 1.14% in controls) at the 17th day of pregnancy (Bulter, 1965, 000013447). At 100 ppm there was a 26.5% reduction of conceptuses. No gross abnormalities were observed in the surviving fetuses and no maternal toxicity was observed.

The above rat studies do not satisfy the Guideline's requirements for teratology testing since they lack necropsy and histopathological examination of the fetuses.

In a 3-generation reproduction study, dicrotophos produced toxic effects on fetuses at 5, 15, and 50 ppm (Eisenland and Logwan 1965, 000013446). No toxic effect was observed at 2 ppm. Insufficient litters were produced, individual litter data were not reported, and the histopathology was only summarized, not reported in detail. Consequently, the study does not satisfy Guidelines requirements for reproduction studies

4. Mutagenicity

An *in vivo* study on induction of chromosomal abberrations was performed in CF$_3$ mice (Snell, 1973, GS0003502). Analytical grade dicrotophos was administered orally in a single oral dose of 5 or 10 mg/kg. The animals were killed after 8 or 24 hours, and chromosomal preparations were made from bone marrow cells. The incidence of chromosome abnormalitites did not differ from that in controls.

A dominent lethal assay of technical dicrotophos was performed in male mice of the CFI strain (Shell, 1974, GS0003506). Single oral doses of 5 or 10 mg/kg or 5 consecutive oral doses of 1 or 2 mg/kg/day were tested. The males were then mated weekly with three female mice per week for eight weeks after dosing. Methyl methonesulphonate, 1 mg/kg I.P. was used as a positive control. Dicrotophos treatment did not effect pregency or result in detectable dominant lethal mutations in comparison with the untreated controls.

Four different mutagenic studies with technical dicrotophos were reported (Shell, 1974, GS0003506):

1. A host mediated assay was conducted with Saccaromyces cerevisise D4(4) in male CFI mice. At single oral doses of 5 or 10 mg/kg, no mutagenic effect was observed.

2. An in vitro study was conducted with Saccaromyces cerevisiae D4(4). No mutagenic effects were observed at concentrations of 30 micrograms/ml, 5 mg/ml, 20 mg/ml or 50 mg/ml.

3. An in vitro test with Serratin marcescenes, Hy a 13, Hy a 21(6) and CV/VC3 742(7). No dose data was given. It was reported that this study was negative.

4. An in vitro test with Samonella typhimurium TA1536, TA1537 and TA1538 was conducted. No dose data was reported. It was reported that the study was negative.

The two studies together satisfy the mutagenicity data requirement.

5. Metabolism

In the male rat, dicrotophos rapidly excreted in the urine mainly as the dimethyl and other hydropholic phosphides and the de-N-methylated dicrotophos (Poonawalla, 1965, 000013450). The compound and its metabolites did not accumulate in tissue and no bioaccumulation occurs. Metabolism studies are needed in female rats.

6. Antidotal Studies

Studies with young adult female rats showed that treatment with a combination of atropine sulfate and the oxine Toxogonin was most effective in decreasing the acute toxic effect of oral dicrotophos (Reiff, 1968, 000013569).

B. Human and Domestic Animal Hazard Assessment

Technical dicrotophos has a high acute oral and acute dermal toxicity. The acute toxicity of dicrotophos falls in Category I for oral LD_{50} and dermal LD_{50}; in Category II for inhalation LD_{50}; and in Category III for eye effects. The Agency believes that the acute hazards are mitigated by the precautionary measures prescribed by product labeling and restricted to use by certified applicators.

The Agency's Pesticide Incident Monitoring System (PIMS, 1981) reported 31 incidents involving dicrotophos during the period 1966 to July, 1981. Twenty two incidents involved dicrotophos alone. The other nine incidents involved dicrotophos in combination with other ingredients. Humans were involved in 13 incidents in which dicrotophos alone was cited as causing the alleged adverse effects. Three of the 13 incidents involved home use of dicrotophos for which dicrotophos is not currently registered. The home related incidents were clearly a misuse since the user disregarded the label instructions. All but one of the remaining ten incidents involved noncertified applicators and were attributed to accidental spills or were of undetermined origin. Seven of the ten incidents involved dermal exposure, two involved eye exposure and one was unknown. Toxic effects included nausea, vomiting, abdominal cramps, troubled breathing, weakness and cramps. No deaths were reported and atropine was administered in five of the incidents to assist in recovery. The one incident involving a certified applicator, occurred as a result of a plane crash during aerial application.

The information available to assess potential hazard as a result of chronic exposure is incomplete (see Chapter III for detailed data requirements). The Agency has an acceptable teratology study in rabbits, which indicated no fetal toxicity or gross teratogenic effects at the dose levels tested. However, an unacceptable chronic feeding study indicated excessive mortality and cholinesterase depression. An unacceptable reproduction study indicated fetotoxic effects at the higher dose levels. The unacceptable studies provide onlysupplementary data and cannot be used to draw conclusions concerning margins of safety.

Data are not available to fully assess the potential for exposure of humans to dicrotophos. Applicator inhalation exposure is possible through foliar application to cotton and soybeans grown for seed and mixing and loading operations. Dermal exposure is possible, but should be mitigated with the labeling requirements for protective clothing. Exposure associated with the injection use of dicrotophos on ornamental trees should be negligible since both the injection unit and the sites (trees) are closed systems. Dietary exposure is possible through dicrotophos residues in cotton and soybean food products. Additional food residue information is being required to support continued use on cotton, and seed soybeans (see Chapter III). The registrant may conduct residue chemistry and applicator exposure studies to determine if there is any human chronic exposure to dicrotophos. If these studies demonstrate that there is no human chronic exposure, chronic toxicity studies will not be required. Conversely, if the potential for chronic exposure is demonstrated the chronic toxicity studies will be required (reference Table III. A-3).

C. Summary of Data Gaps

The following generic data are required: acute oral toxicity in female rats, primary skin irritation, dermal sensitization, subchronic 21-day dermal toxicity at higher doses, teratogenicity in rats, and mutagenicity. An acute inhalation toxicity study and a metabolism study in female rats is required unless the acute oral toxicity study in female rats indicates no sexual difference in oral toxicity. A subchronic 90-day oral study is required unless an acceptable pathology report is provided for Witherup et. al. (1964, 000013441). Chronic feeding, oncogenicity, and reproduction data requirements are reserved pending the results of residue chemistry data requirements on cottonseed, processed cotton seed, soybeans, and proccessed soybeans. These chronic studies will be required if dicrotophos residues appear in these food products.

Additional product specific data will not be required if the severest labeling restriction (i.e., the signal word "DANGER" and a skull and crossbones) appears on the product label.

VII: Residue Chemistry

A. Metabolism in Plants and Animals
B. Analytical Methods
C. Residue Data
D. Summary of Major Data Gaps

A. Metabolism in Plants and Animals

1. Uptake, Distribution, and Metabolism of Dicrotophos in Plants

Cotton plants readily take up ^{32}P-dicrotophos administered by topical application or by seed treatment. Radiolabeled material is partially translocated to new growth, and some of the translocated residue is insecticidal, as determined by aphid bioassay. ^{32}P-Dicrotophos injected into the stems of cotton plants is rapidly transported to leaves, but little radioactivity is found below the site of injection (Lindquist et al., 1965, 000013998).

In addition to the parent compound, nine phosphorus-containing metabolites were identified in extracts of excised cotton leaves that had taken up ^{32}P-dicrotophos through the stem (see Table VII-1).

Table VII-1

Metabolites Recovered from Excised Cotton Leaves Following Uptake of ^{32}P-Dicrotophos[1]

Product	Percent of Applied Dose at Indicated Day After Treatment				
	1	3	7	14	28
Dicrotophos[2]	65.1	37.7	16.0	3.3	
Metabolite I[2]	6.0	5.0	0.8	0.1	0.8[3]
Monocrotophos (Azodrin®)[2]	0.0	2.8	1.6	1.4	
Metabolite IV[2]	0.1	2.2	1.9	1.0	0.0
Unknown A	1.8	12.0	10.8	11.3	4.9
Phosphoric Acid	1.5	5.4	5.8	4.3	2.6
Monomethyl Phosphate	0.0	0.2	0.0	0.1	0.0
Desmethyl Metabolite IV	0.1	1.7	1.4	1.4	0.4
Dimethyl Phosphate	6.3	10.9	10.1	9.0	2.8
Desmethyl Dicrotophos	5.1	5.1	3.6	2.1	1.5
Unextracted Radioactivity	14.0	17.0	48.0	66.0	87.0

[1] From Bull and Lindquist, 1964, 005013986
[2] See figure 1 for structure
[3] Combined dicrotophos, Metabolite I, and monocrotophos.

The large amount of "unextracted radioactivity" was assumed to be due to reincorporation of inorganic ^{32}P-phosphate (Bull and Lindquist, 1964, 005013986). The metabolite present in largest amount in cotton plants 14 or more days after ^{32}P-dicrotophos treatment, "Unknown A," was subsequently identified as the O-glucosyl conjugate of Metabolite I (shown as Conjugate I in Figure VII-1 (Shell, 19??, 00013451; Shell, 1965, 000013506).

A pattern of metabolites similar to that in Table VII-1 was observed in cotton seedlings grown from ^{32}P-dicrotophos-treated seed, and in cotyledons or excised leaves of cotton plants topically treated with ^{32}P-dicrotophos (Bull and Lindquist, 1964, 005013986). In seedlings grown from treated seed, there was little translocation of oxidative metabolites from cotyledons to true leaves

Dicrotophos, Metabolite I, and monocrotophos were identified in extracts of bean plants stem-injected with ^{32}P-dicrotophos. Monocrotophos comprised 10 to 14% of the residue 8 to 12 days after treatment. Metabolites II and III were looked for but not found (Menzer and Casida, 1965, 005014733). Conjugate I, which was identified as a major component of the residue in cotton foliage, would not have been extracted by the methods employed in the above study; however, the formation of Conjugate I in bean plants has subsquently been demonstrated elsewhere (Shell, 19??, 000013451; Shell 1965, 000013506).

The data on the metabolism of dicrotophos cited above and data on the metabolism of monocrotophos (Shell, 1965?, 000013506) indicate that in cotton and beans, dicrotophos is metabolized by oxidative N-demethylation (Figure VII-1). Dicrotophos and the metabolites of the N-demethylation pathway are in turn readily hydrolyzed at the methyl-phosphate, vinyl-phosphate, and amide bonds (Figure VII-2). Dicrotophos and its unhydrolyzed metabolites are potent cholinesterase inhibitors (Menzer and Casida, 1965, 005014733) and maytherefore be of concern if present on any commodity in other than negligible amounts. Conjugates I and II, although not potent cholinesterase inhibitors themselves, may be of concern because they may be reconverted to Metabolites I and II, which are strong inhibitors.

In cotton foliage and in whole bean plants, the significant cholinesterase-inhibiting components of the residue are dicrotophos, the hydroxymethyl analog of dicrotophos (Metabolite I), and the glucosyl conjugate of the analog (Conjugate I). The half-life of the sum of these residues in cotton plants is approximately 7 days (calculated from data in Table VII-1). The apparent half-life of dicrotophos per se in cotton foliage is 1 day for the first 4 days after treatment and 3 to 5 days from days 0 to 14 (calculated from data in Table VII-1, and Shell, 1962, 00013684). The half-life of Conjugate I in cotton foliage is not less than 11 days (calculated from data in Table VII-1).

Cottonseed was not analyzed in any of the studies discussed in this section. The Agency thus has no data on the total dicrotophos-equivalent residue level in seed from dicrotophos-treated plants, or on whether any of the metabolites in cotton foliage are transferred to seed.

2. Metabolism of Dicrotophos in Food-Producing Animals

Milk and feces from cows maintained for 28 days on 15 ppm dicrotophos (approximately 0.23 mg/kg body weight) contained no detectable (<0.002 ppm for milk,

<0.004 ppm for feces) dicrotophos or monocrotophos. Urine contained 2 to 5% of the ingested dose as monocrotophos and dicrotophos (70% and 30%, respectively, of the material recovered from the urine). Analyses for other metabolites were not performed (Johnson and Bowman, 1968, 005012698).

Lactating goats orally dosed once with capsules containing 1 or 2 mg ^{32}P-dicrotophos per kilogram of body weight excreted, within 72 hours, 78 to 90% of the dose in the urine, 0.8 to 1.3% in the feces, and 0.72% in the milk. Some chloroform-soluble products of goat metabolism are shown in the following table (Menzer and Casida, 1965, 005014733):

Table VII-2

Metabolites of Dicrotophos in Urine and Milk of a Lactating Goat[1]

Product	Urine[2]	Milk[3]
Hydrolysis Products	7.8	------
Dicrotophos	0.10	0.0208 (1 hr)
Metabolite I	0.00	<0.0001 (1-24 hr)
Monocrotophos	1.5	0.0760 (2 hr)
Metabolite II	0.16	0.146 (6 hr)
Metabolite III	0.53	0.0028 (4 hr)
Unidentified	0.48	0.0296 (4 hr)

1/ From Menzer and Casida, 1965, 005014733
2/ Percent of administered dose, collected 1-2 hours after treatment
3/ Maximum ppm attained, measured at indicated time after treatment

Residues of all compounds in goat milk had declined to <0.002 ppm by 24 hours after treatment. Tissue samples were not analyzed (Menzer and Casida, 1965, 005014733). Conjugates, if present, would not likely have been chloroform-soluble.

Although there are no data on the nature of tissue residues in food-producing animals orally dosed with dicrotophos, there are some data on other animals that show that tissue residues do result from dicrotophos feeding. ^{32}P-Labeled residues were detected in tissues of rats orally dosed with 1 mg dicrotophos/kg body weight (approximately 10-20 ppm in the diet); however, the residues were not identified. ^{32}P-Residues were highest in liver and kidney (0.62 and 0.34 ppm dicrotophos equivalents, respectively; Menzer and Casida 1965, 005014733).

The data, though not extensive, indicate that metabolism of dicrotophos in animals is similar to that in plants.

B. Analytical methods

Methods for the determination of dicrotophos residues fall into two categories: cholinesterase inhibition methods and gas-liquid chromatographic (GLC) methods. Residue methods MMS 40/61 (Shell, 1962, 000013682), MMS 40/63

(Shell,1963, 000013472), and MMS 40/64 (Shell, 1964, 000013703) are very similar enzymatic methods that determine dicrotophos per se but not hydroxylated metabolites or conjugates of hyroxylated metabolites. Samples are extracted with chloroform, the solvent exchanged to hexane, and the hexane extracted with water. Dicrotophos in the extract is assayed enzymatically with human plasma cholinesterase. Sensitivites of the methods are 0.04 ppm for most crops, 0.02 ppm for milk, and 0.1 ppm for animal tissues.

Method MMS-66/65 (Shell 1965, 000013474) is similar to the above methods but includes a column chromatographic cleanup step to remove interfering pesticides. Sensitivity is 0.05 ppm for crops and 0.01 ppm in milk.

Method MMS-70/65 (Shell, 1965, 000013456) determines Conjugate I. Crops are extracted with water, and the extract is washed with methylene chloride and hexane. The extract is treated with HCl to hydrolyze the conjugate to Metabolite I and immediately assayed with fly head cholinesterase. The method is sensitive to as little as 0.1 microgram of the conjugate.

Methods MMS-R-245-1 (Shell, 1970, 000014005) and MMS-R-245-2 (Shell, 1975, 000013517) also determine Conjugate I. The glucoside present in cleaned up aqueous extracts is hydrolyzed with HCl to Metabolite I, which is immediately derived *in situ* to form a thioether. The derivative is cleaned up by thin-layer chromatography (TLC) and assayed directly on the TLC plates with human plasma cholinesterase. Sensitivity is 0.06-0.1 ppm for crops.

Methods MMS-65/65 (Shell, 1965, 000013453) and MMS-65/66 (Shell, 1966, 000013967) determine dicrotophos, monocrotophos, and Metabolites I and II, but do not determine the glucosyl conjugates of the analogs (Conjugates I and II). Crops are extracted with chloroform, and the solvent exchanged to water. The aqueous solution is washed with carbon tetrachloride or hexane to remove interferences. The extract is assayed enzymatically with fly head cholinesterase to determine total anticholinesterase activity. By making the assumption that all cholinesterase inhibition is due to monocrotophos, the least inhibitory of the four compounds detected, a maximum residue concentration can be calculated from the data.

Methods PMS-G-902/66 (Shell, 1966, 00013969), PMS-G-918-69 (Shell 1969, 000014006; Shell, 1969, 000013999), and MMS-R-332-1 (Shell 1973, 000013516) are related GLC methods suitable for the determination of dicrotophos and monocrotophos but not for other metabolites or their conjugates. Sensitivities are 0.01-0.05 ppm for both dicrotophos and monocrotophos.

Volume II of the Pesticides Analytical Manual (PAM II) lists 2 methods of enforcement of tolerances, one of which is the GLC method PMS-G-918/69 (Shell 1969, 000014006; Shell 1969, 000013999) mentioned above. The other method is the GLC method of Watts et al. (1969, 005002358), in which crops are extracted with ethyl acetate, the extracts cleaned up on charcoal columns, and the cleaned up extracts analyzed by GLC with thermionic detection. Sensitivity of the method is 0.01 ppm for cottonseed. Both of these methods detect dicrotophos and monocrotophos, but not other cholinesterase-inhibiting metabolites.

No single method discussed in this section is capable of determining dicrotophos and all of its cholinesterase-inhibiting metabolites. For obtaining residue data, two or more of the methods may be combined to determine the residue of concern on a commodity. For enforcement purposes, the GLC methods described in PAM II are suitable for the determination of dicrotophos and monocrotophos. If other metabolites are shown to be components of the residue of concern in a particular commodity, then additional methods for their determination will be necessary. These additional enforcement methods must be specific; cholinesterase inhibition methods will not be acceptable.

C. Residue Data

1. Residues in Plants

a. Cotton

Soluble concentrates containing dicrotophos may be applied by ground or aerial equipment to cotton at rates up to 0.5 lb per acre per application. Cottonseed may not be harvested within 30 days of last application, and livestock are not to be grazed on treated fields. A tolerance of 0.05 ppm (negligible residue) has been established for residues of dicrotophos per se on raw cottonseed.

Table VII-3 summarizes cottonseed residue data.

Table VII-3

Available Residue Data on Cottonseed

SAMPLE	Preharvest Interval (days)	Application Rate(s) (lb/acre)	Residues[1/] of Dicrotophos (ppm) <0.05	>0.05	REF.
Cottonseed	0-10	0.5-1.0	5	15	a
Cottonseed	12-30	0.5-1.0	18	0	a
Cottonseed	5-12	1.0	7	0	b
Cottonseed	14-50	1.0	4	0	c
2/ Cottonseed	14-50	1.0	4	0	c

1/ All data reflect ground application of a water-soluble concentrate. Unless otherwise indicated, residues were analyzed by methods specific for dicrotophos per se (MMS-40/61 or MMS-40/63).
2/ Analysis is specific for Conjugate I (MMS-R-245-1).
a/ Shell, 1962, 00013684
b/ Shell, 1968, 00014000
c/ Shell 1969, 00013997

The data indicate that residues of dicrotophos per se on raw (unprocessed) cottonseed do not exceed 0.05 ppm, 14 or more days after application of dicrotophos at rates up to 0.5 lb per acre per application; however, dicrotophos per se may not be the only significant component of the residue in cottonseed. The major residue in cotton foliage 14 or more days after dicrotophos application is the glucosyl conjugate of the hydroxymethyl analog of dicrotophos (Conjugate I). If the conjugate is also the predominant residue in cottonseed, then the bulk of the data, obtained by methods that detect only dicrotophos per se, is invalid. The conjugate was not detected (<0.05 ppm) in 4 samples analyzed by a method specific for the conjugate; however, these few samples are clearly inadequate to support the tolerance.

Additional residue data for cottonseed are required. Seed from dicrotophos-treated plants should be analyzed by methods that determine dicrotophos, monocrotophos, the hydroxymethyl analogs of dicrotophos and monocrotophos, and the glucosyl conjugates of the analogs. The residue data will not be required if metabolism data (see Table III. A-4) demonstrating the absence of dicrotophos metabolites in cottonseed are submitted.

If detectable residues of dicrotophos or its metabolites are shown to be present in cottonseed as a result of the registered use, then a fractionation study will be necessary. For this study, residue-bearing seed, or untreated seed fortified with each component of the residue found on the raw commodity,should be used.

There are several products registered for use on cotton that contain mixtures of dicrotophos and either toxaphene or tetradifon. Residues of dicrotophos from use of these products are not expected to exceed those from use of a product containing dicrotophos as the sole active ingredient provided the conditions of use are the same for the two types of products.

To support aerial use of dicrotophos on cotton, data reflecting this mode of application should be submitted.

b. Pecans

A pending application would permit injection of dicrotophos into the scaffold limbs of pecan trees at rates up to 0.004 lb active ingredient per 6 inches of scaffold limb circumference. Two treatments per year would be permitted, and nuts could not be harvested within 120 days of last treatment. A tolerance of 0.05 ppm is proposed for residues of dicrotophos and its metabolite monocrotophos, on pecans. Table VII-4 summarizes pecan residue data.

Table VII-4

Available Residue Data on Pecans[1/]

SAMPLE	PHI (days)	RATES (lb/6"circ)	NUMBER OF SAMPLES ANALYZED DICROTOPHOS <0.01 ppm	MONOCROTOPHOS <0.02 ppm	REF.
Nut meats	112-120	0.004-0.016	5/5	5/5	a
Shells	112-120	0.004-0.016	5/5	5/5	a
Shucks	112-120	0.004-0.016	3/3	3/3	a

1. Data reflect limb injection of a water-soluble concentrate. Residues were analyzed by a method specific for dicrotophos and monocrotophos (MMS-R-332-1).

a. Data from pesticide Petition 0E2415, (GS0003504)

Dicrotophos and monocrotophos were not detected in pecans 120 days after treatment with dicrotophos at rates up to 0.016 lb per 6 inches of scaffold limb circumference; however, there are no metabolism data indicating that residues in pecans resulting from injection of dicrotophos are limited to the parent compound and monocrotophos.

c. Soybeans

Dicrotophos is registered for use on soybeans grown for seed at rates up to 1 lb per acre application. There is a 30-day pre-harvest interval and livestock may not be grazed or fed on treated plants or seed.

There is no tolerance for residues of dicrotophos on soybeans. At the time that dicrotophos was registered for this use, the application of pesticides to crops grown for seed was considered a non-food use. Subsequent experience has shown that, upon leaving grower control, residue-bearing seed may be used for food or feed, and consequently, a tolerance proposal is now required for pesticides applied to soybeans grown for seed.

For the continued registration of dicrotophos on seedcrop soybeans, a tolerance proposal with supporting data is required. This should include analysis of the raw agricultural commodity for residues of dicrotophos and its cholinesterase-inhibiting metabolites, and residue data on processed oilseed fractions if real residues are found in the seed. Data on residues in meat and milk may also be required if significant residue levels are present in soybeans or soybean fractions.

2. Residue Storage Stability

There are no valid data on the stability of dicrotophos or its cholinesterase-inhibiting metabolites during long-term storage of residue-bearing commodities.

3. Residues of Dicrotophos in Food-Producing Animals

Three lactating Holstein cows were fed, 5, 15, or 45 ppm dicrotophos in the diet for 13 days. Milk collected during the feeding period was analyzed for dicrotophos per se, but none was detected (<0.01 ppm) in any sample. The cow maintained on 5 ppm dicrotophos was sacrificed immediately after the 13-day feeding period. No detectable dicrotophos per se was found in body fat, omental fat, liver, kidney, heart, brain, or muscle; however, the method used for analysis of tissue residues is somewhat insensitive (0.1 ppm detection limit). The remaining 2 cows, slaughtered after a 4-day withdrawal period, also contained no detectable dicrotophos per se in any of the tissues analyzed (Pankaskie, 1962, 000013440).

In a later study, silage containing dicrotophos at levels of 13 to 18 ppm (average of 15 ppm, approximately equivalent to 0.23 mg/kg of body weight) was fed to 4 lactating Jersey cows for 28 days. Milk was monitored for dicrotophos and monocrotophos throughout the feeding period. Neither compound was detected (<0.002 ppm) in any sample from any of the 4 cows (Johnson and Bowman, 1968, 005012698).

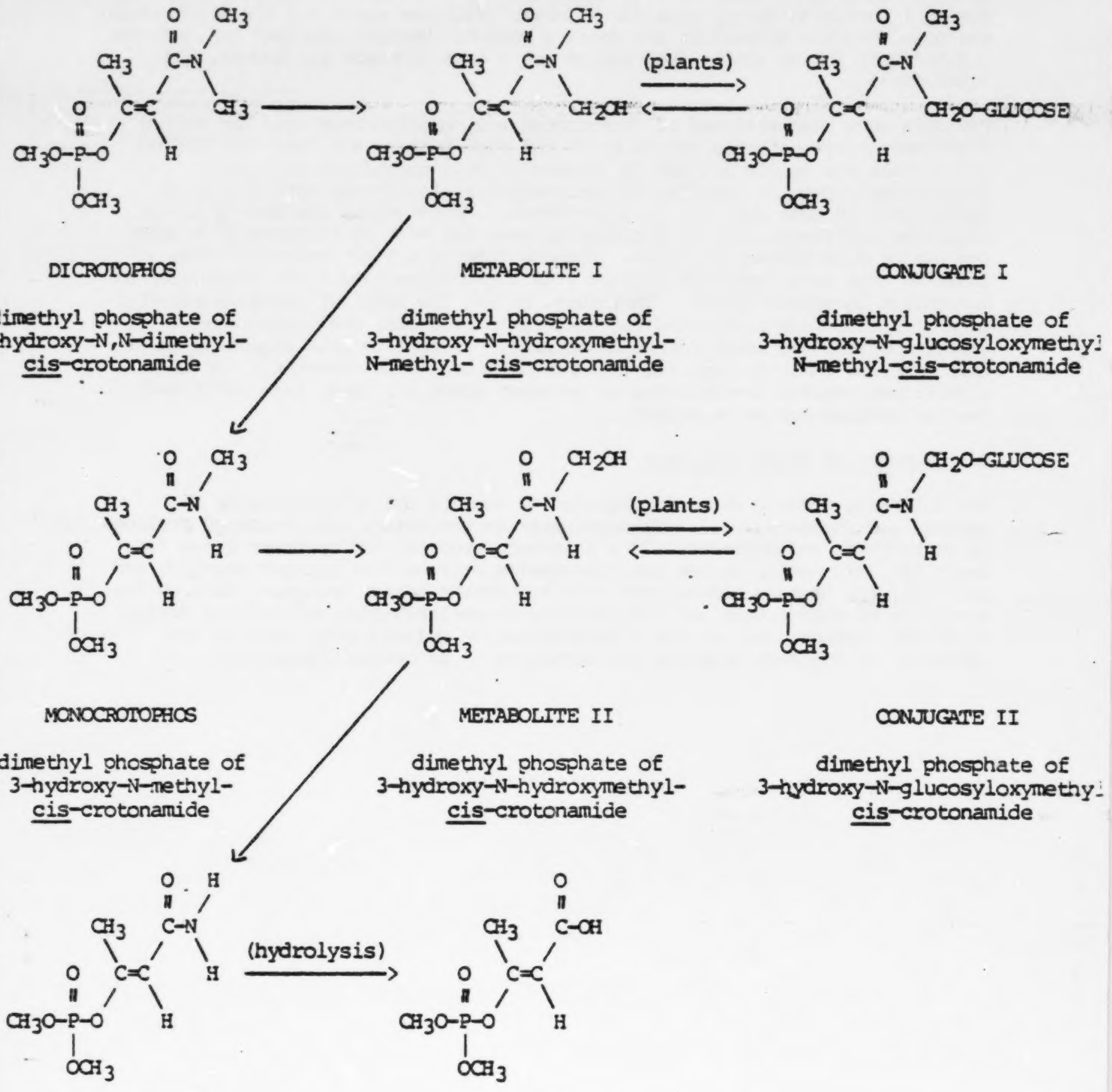
The data show that residues of dicrotophos and monocrotophos will not exceed 0.002 ppm in milk of cows fed up to 15 ppm dicrotophos, and that dicrotophos per se will not exceed 0.1 ppm in tissues of cows maintained on 5 ppm dicrotophos. Data on residues of cholinesterase-inhibiting metabolites of dicrotophos in meat have not been submitted. Nevertheless the Agency is not requiring additional data on residues in meat and meat by-products to support the use of dicrotophos on cotton. Because limited animal metabolism data indicate that total residues derived from dicrotophos have a low propensity to accumulate in animal tissue. Therefore, at the low level of residues expected in animal feed from cottonseed and cottonseed products, cholinesterase-inhibiting residues would not be detectable. If residue data requested under this standard indicate that the cottonseed tolerance is inadequate, or if significant residue levels occur on soybeans grown for seed, then additional feeding studies may be necessary.

D. Summary of Major Data Gaps

The following generic data are required to support use of dicrotophos on cotton, and soybeans: (1) additional data on the nature and amount of residues in cottonseed, and soybeans; (2) a tolerance proposal for soybeans grown for seed; (3) information on how residue samples were handled between sampling and analysis; for samples stored more than two months before analysis, data on the stability of dicrotophos and its cholinesterase-inhibiting metabolites during long-term storage; and (4) for a representative oilseed crop, data on the carryover of residues from the raw commodity to processed commodities.

Figure VII-1

Oxidative N-Demethylation of Dicrotophos in Cotton, Beans, and Mammals



DICROTOPHOS

dimethyl phosphate of
-hydroxy-N,N-dimethyl-
cis-crotonamide

METABOLITE I

dimethyl phosphate of
3-hydroxy-N-hydroxymethyl-
N-methyl- *cis*-crotonamide

CONJUGATE I

dimethyl phosphate of
3-hydroxy-N-glucosyloxymethyl
N-methyl-*cis*-crotonamide

MONOCROTOPHOS

dimethyl phosphate of
3-hydroxy-N-methyl-
cis-crotonamide

METABOLITE II

dimethyl phosphate of
3-hydroxy-N-hydroxymethyl-
cis-crotonamide

CONJUGATE II

dimethyl phosphate of
3-hydroxy-N-glucosyloxymethyl
cis-crotonamide

METABOLITE III

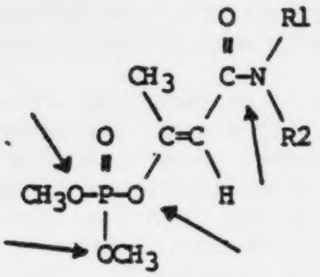
dimethyl phosphate of
-hydroxy-*cis*-crotonamide

METABOLITE IV

dimethyl phosphate of
3-hydroxy-*cis*-crotonic acid

Figure VII-2

Sites of Hydrolytic Attack of Dicrotophos and Its Derivatives.


O
R1
CH3
C-N
O
C=C
R2
CH3O-P-O
H
OCH3

VIII: Ecological Effects

A. Ecological Effects Profile
B. Ecological Effects Hazard Assessment
C. Summary of Major Data Gaps

A. Ecological Effects Profile

1. Effects on Birds

The minimum data required for establishing the acute toxicity of dicrotophos to birds are the results of one single-dose oral LD_{50} study on either an upland game species (preferably bobwhite or other native quail, or the ring-necked pheasant) or waterfowl (preferably mallard duck) (Section 163.71-1).

There is sufficient information to characterize the acute oral toxicity of dicrotophos to birds as very highly toxic. The lowest LD_{50} resulted from avian testing on the Toulouse goose; however, an insufficient number of birds used in the testing makes this study inadequate to satisfy the Guidelines requirement. Although neither of the other two studies is adequate to satisfy the Guidelines requirement, when considered together they are sufficient to fulfill the avian acute oral LD_{50} requirement. The studies are listed in Table VIII-1.

Table VIII-1 Avian Single-dose oral LD_{50} (Dicrotophos)

Species	%a.i.	Result	Author	Date	ID
Mallard duck (Anas platy-rhychos)	98	4.24 mg/kg (3.06-5.88)	Hudson et al.	1979	005008363
Toulouse goose	Tech. % N/A	1.22 mg/kg	Doyle and Elsea	1963	000013439
Mallard duck	98	4.24 mg/kg	U.S. Fish and Wildl. Ser.	1966	000014011
Ring-necked pheasant	"	3.21 mg/kg	"	"	"
Chukar	"	9.63	"	"	"
Japanese quail	"	4.32	"	"	"
Pigeon	"	2.38	"	"	"
Sparrow	"	3.00	"	"	"

The minimum data required for establishing the subacute (dietary) toxicity of dicrotophos to birds are the results from at least two avian dietary toxicity studies (LC_{50} value) (Section. 163.71-2). These tests should be conducted with one upland game species (preferably bobwhite or other native quail, or a ring-necked pheasant), plus one waterfowl (preferably mallard duck).

There is sufficient information to characterize the subacute dietary toxicity of dicrotophos to quail and pheasant as very highly toxic and as highly toxic to mallard ducks. The Guidelines requirement regarding subacute toxicity to birds is satisfied. The data are listed in Table VIII-2.

Table VIII-2

Avian Subacute Dietary LC_{50} (Dicrotophos)

Species	% a.i.	Result	Author	Date	ID
Japanese quail (c. coturnix japonica)	Tech. % n/a	52 ppm (38-71)	Shellenberger et al.	1970	005017969
Bobwhite quail (Colinus virginianus)	Tech. % n/a	13 ppm (8-20)	Gough et al.	1967	000013707
Mallard duck (Anas platyrhychos)	85%	144 ppm (110-185)	Hill et al.	1975	000022923
Ring-necked pheasant (Phasianus colchicus)	85%	44 ppm (38-51)	Hill et al.	1975	000022923
Japanese quail	85%	32 ppm (26-39)	Hill et al.	1975	000022923

Data addressing effects on avian reproduction may be required to support the registration of formulated products (Section 163.71-4) since dicrotophos may be applied repeatedly throughout the growing season and is very highly toxic to birds. In a 5-week study (3-week treatment period followed by 2 weeks of observation) on Japanese quail, the reproductive effects of dicrotophos on Japanese quail were studied (Shellenberger, 1966, 005013052). At 50 ppm dietary exposure, food consumption and egg production were markedly reduced; egg production was completely inhibited after the fifth day; and 17-30% weight loss and 58-75% mortality were observed. At 0.5 and 5.0 ppm dietary exposure, food consumption, egg production, and body weight were normal throughout the test period. Whole blood cholinesterase was completely inhibited at 5 and 50 ppm dietary exposure, but no inhibition was observed at 0.5 ppm.

This study is not sufficient to fulfill the Guidelines requirement for an avian reproduction study since the treatment period was not of adequate length to assess reproductive effects. However, the study does indicate that dicrotophos may have adverse effects on avian reproduction.

Two avian field studies have been reviewed but are not acceptable since insufficient pre- and post-treatment surveys were conducted. While not adequate to fulfill any Guidelines requirements, the results of these field tests do indicate that dicrotophos may have adverse effects on avian species through both acute toxicity and decreased nest success. One field study observed the effects of dicrotophos on horned larks, meadowlarks, lark sparrows and loggerhead shrike, with dicrotophos sprayed on grassland at 2 ounces per acre (McEwen and Haegele, 1968, 000013702). The number of birds decreased significantly ($P<0.01$) from 16 per half-mile transect before spraying to 10 birds per half mile transect four days after spraying. The four bird nests under observation were abandoned or the nestlings disappeared following the spraying. Only one bird carcass was found during post spray searches, but symptoms of poisoning were observed in numerous birds.

The other field study noted the effects of dicrotophos on chipping sparrows, juncos, white-crowned sparrows, Mac Gillivray warblers, mourning doves, linnets, and Inca doves with dicrotophos sprayed on a lemon orchard at 2 lbs. technical dicrotophos per acre (Simkover and Bishop, 1971, 000013511). Twenty-four hours after treatment 16 dead and 5 moribund birds were found. The next day 9 more dead birds were found.

Two miscellaneous studies, which address toxicity to avian embryos and percutaneous toxicity, were reviewed. One study observed the effects of 250 ug of dicrotophos injected into 3-day old quail eggs (Meiniel, 1978, 005015806). Eggs were sacrificed at 10 or 11 days and anomalies of beak, legs, and neck were noted. Cervical anomolies were due to retardation of development of the skeletal parts and to twistings of the spinal column.

Another study resulted in a 24-hour percutaneous LD_{50} of 14.2 mg/kg in mallards exposed to 98% technical dicrotophos (Hudson, 1979, 005008363).

These studies do not follow any standard protocol and are not normally required under the Guidelines.

2. Effects on Freshwater Invertebrates

The minimum data required for establishing the acute toxicity of dicrotophos to freshwater invertebrates is the result of one 48-hour study with technical dicrotophos on a representative native freshwater invertebrate, preferably *Daphnia magna* (Section 163.72-2). The acceptable studies are listed in Table VIII-3.

Table VIII-3

Acute Toxicity Studies on Freshwater Invertebrates (Dicrotophos)

Species	%a.i.	LC_{50}	Author	Date	ID
Gammarus fasciatus	80%	2600 ppb (2100-3200)	Sanders	1972	005017538
Gammarus lacustris	80%	540 ppb (400-730)	Sanders	1969	005009242
Pteronarcys californica	80%	430 ppb (340-540)	Sanders and Cope	1968	005010360

The Guidelines requirement for acute toxicity to freshwater invertebrates is not satisfied since the studies were conducted with adult rather than immature invertebrates. Immature aquatic invertebrates are assumed to be more sensitive than adults; their LC_{50} would enable a standard hazard assessment to be performed. There is, however, sufficient information to characterize technical dicrotophos as moderately to highly toxic to freshwater invertebrates.

3. Effects on Freshwater Fish

The minimum data required for establishing the acute toxicity of dicrotophos to freshwater fish are the results of two 96-hour studies with technical dicrotophos; one coldwater species (preferably rainbow trout) and one warmwater species (preferably bluegill sunfish) (Section 163.72-1). The acceptable acute toxicity data are listed in table VIII-4.

Table VIII-4

Fish Acute LC_{50} (Dicrotophos)

Species	%a.i.	LC_{50}	Author	Date	ID
Bluegill (*Lepomis macrochirus*)	80%	24.2 ppm (14.3-41.1)	Johnson and Finley	1980	GS0003503
Rainbow trout *Salmo gairdneri*)	90%	6.3 ppm	Johnson and Finley	1980	GS0003503
Channel catfish (*Ictalurus punctatus*)	90%	7.7 ppm (4.0-13.8)	Johnson and Finley	1980	GS0003503

Table VIII-3

Acute Toxicity Studies on Freshwater Invertebrates (Dicrotophos)

Species	%a.i.	LC_{50}	Author	Date	ID
Gammarus fasciatus	80%	2600 ppb (2100-3200)	Sanders	1972	005017538
Gammarus lacustris	80%	540 ppb (400-730)	Sanders	1969	005009242
Pteronarcys californica	80%	430 ppb (340-540)	Sanders and Cope	1968	005010360

The Guidelines requirement for acute toxicity to freshwater invertebrates is not satisfied since the studies were conducted with adult rather than immature invertebrates. Immature aquatic invertebrates are assumed to be more sensitive than adults; their LC_{50} would enable a standard hazard assessment to be performed. There is, however, sufficient information to characterize technical dicrotophos as moderately to highly toxic to freshwater invertebrates.

3. Effects on Freshwater Fish

The minimum data required for establishing the acute toxicity of dicrotophos to freshwater fish are the results of two 96-hour studies with technical dicrotophos; one coldwater species (preferably rainbow trout) and one warmwater species (preferably bluegill sunfish) (Section 163.72-1). The acceptable acute toxicity data are listed in table VIII-4.

Table VIII-4

Fish Acute LC_{50} (Dicrotophos)

Species	%a.i.	LC_{50}	Author	Date	ID
Bluegill (*Lepomis macrochirus*)	80%	24.2 ppm (14.3-41.1)	Johnson and Finley	1980	GS0003503
Rainbow trout *Salmo gairdneri*)	90%	6.3 ppm	Johnson and Finley	1980	GS0003503
Channel catfish (*Ictalurus punctatus*)	90%	7.7 ppm (4.0-13.8)	Johnson and Finley	1980	GS0003503

The Guidelines requirement for both coldwater and warmwater fish is fulfilled. There is sufficient information to characterize technical dicrotophos as moderately toxic to freshwater fish.

4. Effects on Nontarget Insects

Dicrotophos was shown to be highly toxic to alkali bee (Moradeshaghi, 1974,005015679) alfalfa leafcutter bee (Lee and Brindley, 1974, 005015678), and honey bee (Clinch and Palmer-Jones, 1971, 005013577; Clinch et al., 1973 005009353). The latter two studies also showed that dicrotophos residual toxicity to honey bees may persist for a week or more under certain field conditions.

There are presently no Guidelines requirements for evaluating toxicity to nontarget insects. However, there is sufficient information to characterize dicrotophos as highly toxic to alkali bee, alfalfa leafcutter bee, and honey bee. Data also indicate that toxicity to honey bees may persist for a week or more under certain field conditions. The results of these studies are summarized in Table VIII-5.

Table VIII-5

Toxicity Studies on Beneficial Insects With Dicrotophos

Species	Formulation	Results	Author	Date	ID
Alkali bee (Nomia melanderi)	Technical	LD50=1.75 ug/g (male), 1.52ug/g (female)-highly toxic	Moradeshaghi et al.	1974	005015679
Alfalfa leafcutter bee (Megachile pacifica)	Technical	Estimated LD50= 1.2 ug/g (male)-highly toxic	Lee and Brindley	1974	005015678
Honey bee (Apis mellifera)	85% EC	Bee toxicity persisted for 2 weeks under field conditions.	Clinch and Palmer-Jones	1971	005013577
Honey bee	85% EC	moderately to highly toxic to bees for 5 days following application.	Clinch et al.	1973	005009353

B. Ecological Effects Hazard Assessment

Due to the limited amount of environmental fate information available, a detailed hazard assessment for fish and wildlife cannot be made at this time. The data do indicate that the acute oral and subacute dietary toxicity of dicrotophos to birds is very high. Although the RPAR criterion for subacute dietary toxicity to birds cannot be fully evaluated without: the required environmental fate data, a field test on birds, and information on the frequency of repeat applications, an examination of the available toxicity data indicates that the avian dietary criterion may be exceeded in the cotton and soybean use patterns. Also, dicrotophos may have adverse effects on avian reproduction and has been shown to be toxic to bees. The Agency's Pesticide Incident Monitoring System (PIMS, 1981) reported three incidents involving dicrotophos alone. One incident involved the discovery of dead birds in a city park; the other two incidents involved damage to bee hives located in the vicinity of aerial application of dicrotophos to cotton fields. Accordingly, appropriate label warnings for birds and bees will be required for reregistration.

C. Summary of Major Data Gaps

The major data gaps for this chemical are: acute toxicity to aquatic invertebrates and a field test on birds. Data requirements for avian reproduction are reserved pending the results of the required environmental fate data.

IX. Case Bibliography

Guide to Use of This Bibliography

1. Content of Bibliography

The Agency bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this Standard. The bibliography is divided into two sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the Standard;, and (2) citations examined and judged to be inappropriate for use in developing the standard. This second part of the bibliography exists in the Agency's files and does not accompany this standard. Interested parties may request a copy from the Agency. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions,.and the published technical literature.

2. Units of Entry

The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries on them, treating them as a single study.

3. Identification of Entries

The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit identifier. This number is unique to the citation, and should be used at any time specific reference is required. This number is called the "Master Record Identifier," or "MRID." It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to used whenever specific reference is needed.

4. Form of the Entry

In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI) and was expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

a. Author

Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date

When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title

This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between brackets.

d. Trailing Parentheses

For studies submitted to us in the past, the following elements describing the earliest known submission (in addition to any self-explanatory text) are included within the trailing parentheses.

1) Submission Date. Immediately following the word "received" appears the date of the earliest known submission.

2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

4) Volume Identification. The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z and the 27th 123456-AA.

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Section 1

Citations Considered To Be Part Of The Data Base Supporting Registration Under The Standard

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Section 2
Citations Examined and Judged To Be Inappropriate For Use In Developing This Standard

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